

insignificant result is more likely be due to lack of power rather than due to true absence of difference between the groups.

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REFERENCES

1. Mahajan V, Sajan SS, Sharma A, Kaur J. Ringers lactate vs normal saline for children with acute diarrhea and severe dehydration- A double blind randomized controlled trial.

- Indian Pediatr. 2012;49:963-8.
2. Vickers AJ. The use of percentage change from baseline as an outcome in a controlled trial is statistically inefficient: a simulation study. *BMC Med Res Methodol.* 2001;1:6.
3. Vickers AJ, Altman DG. Statistics notes: Analysing controlled trials with baseline and follow up measurements. *BMJ.* 2001;323:1123-4.
4. Van Breukelen GJ. ANCOVA versus change from baseline: more power in randomized studies, more bias in nonrandomized studies [corrected]. *J Clin Epidemiol.* 2006;59:920-5.
5. Begg CB. Suspended judgment. Significance tests of covariate imbalance in clinical trials. *Control Clin Trials.* 1990;11:223-5.
6. Senn S. Testing for baseline balance in clinical trials. *Stat Med.* 1994;13:1715-26.

Preventing Paracetamol Overdose in Children: Do We Really Need a 500 mg/5mL Preparation?

Although the safety profile of paracetamol compared to other analgesics is excellent, acute overdosage and therapeutic excesses are commonly recognized problems [1]. The recommended dose of paracetamol is 10-15 mg/kg/dose and not exceeding 60 mg/kg/day [2]. In the United Kingdom legislations have been introduced to restrict the pack size of acetaminophen tablets that is available for sale. Its impact on reducing acetaminophen toxicity is yet to be determined convincingly as few studies indicate a reduction in number of fatal cases of toxicity and reduction in hospitalizations to liver units, whereas some studies indicate that there has actually been an increase in the number of cases [3].

In India, it is surprising to find that the drug controller of India has approved a formulation for oral paracetamol suspension having strength of 500mg/5ml by a reputed Indian company specializing in different paracetamol dose preparations. Is there a perceived need to have such a preparation? In our opinion It is likely to cause more confusion and more chances of drug overdosage by the unassuming lay public if purchased over the counter for self medication. Having such a preparation at home, especially without child resistant caps could also lead to unintentional poisonings among infants and young

children. For an infant weighing ten kilograms, an acute intake of as low as ten milliliters of the preparation may prove fatal. There is no justification for its use whatsoever as syrups or suspensions are costlier than tablets and most children as well as majority of caregivers prefer tablets over syrups or suspensions [4]. Hence there is an urgent need to rethink on the need for introducing such formulations and to withhold licensing of such formulations in future considering its potential for causing overdosage and toxicity.

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REFERENCES

1. Kelly DA, Mayer D. Liver transplantation. *In: Kelly DA, editor. Diseases of the Liver and Biliary System in Children.* Second ed. USA: Blackwell Publishing Ltd; 2004. p. 378-401.
2. Russell FM, Shann F, Curtis N, Mulholland K. Evidence on the use of paracetamol in febrile children. *Bull World Health Organ.* 2003;81:367-72.
3. Hawkins LC, Edwards JN, Dargan PJ. Impact of restricting paracetamol pack sizes on paracetamol poisoning in the United Kingdom: a review of the literature. *Drug Saf.* 2007;30:465-79.
4. Anshah EK, Gyapong JO, Agyepong IA, Evans DB. Improving adherence to malaria treatment for children: the use of prepacked chloroquine tablets vs chloroquine syrup. *Trop Med Int Health.* 2001;6:496-504.